

Northwest Community Clinical Oncology Program (NWCCOP)
315 Martin Luther King Jr., Way
Tacoma, WA 98405
Phone: (253) 403-1461
Fax: (253) 403-1615

Sponsored and Funded by the National Cancer Institute

CONSENT FORM

CTSU IBCSG 24-02: A phase III trial evaluating the role of ovarian function suppression and the role of Exemestane as adjuvant therapies for premenopausal women with endocrine responsive breast cancer.

INVESTIGATORS:

Lauren K. Colman, MD, Chris Chen, MD, Jay Klarnet, M.D., W. Welby Cox, MD, FACP,

Xinda Wang, MD, 1003 South 5th Street-3rd Floor, Tacoma, WA 98405 (253) 403-1677.

Robert McCroskey, MD, Sibel Blau, MD, Andrea Rose, MD, 400-15th Avenue SE, Puyallup, WA 98372 (253) 841-4296.

Frank Senecal, MD, Thomas Baker, MD, Lorrin Yee, MD, Moacyr Oliveira, MD
1624 South I Street, Tacoma, WA 98405 (253) 383-3366.

Paul Robertson, MD, Steven Gorton, MD, James Lechner, MD, Harry Griffith, MD,
Xingwei Sui, MD, 4525 Third Ave. SE, Suite 200, Lacey, WA 98503 (360) 754-3934.

John Gallucci, MD, John Rieke, MD, 1003 South 5th Street, 1st Floor, Tacoma, WA
98405 (253) 403-4994.

Suppression of Ovarian Function Trial (SOFT)

CTSU: IBCSG 24-02: A Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane Adjuvant Therapies for Premenopausal Women with Endocrine Responsive Breast Cancer

Tamoxifen versus Ovarian function suppression + tamoxifen versus Ovarian function suppression + exemestane

This is a clinical trial (a type of research study). Clinical trials include only patients who choose to take part. Please take your time to make your decision. Discuss it with your doctor, your friends and your family.

You are being asked to take part in this study because you have breast cancer which has been confined to the breast and lymph nodes under the arm, and have no evidence of cancer elsewhere (early stage breast cancer). To be eligible for this study you must have had either a mastectomy (removal of the entire breast and underlying tissue), in which case radiation therapy is up to you and your doctor, OR breast conserving surgery (such as lumpectomy; removal of the tumor and surrounding tissue but not the entire breast) with radiation therapy done or planned. Only women who are pre-menopausal and whose tumors have hormone receptors can take part in this study. The pathologist (doctor who examines cancer tissue under a microscope) will have determined whether or not your breast tumor expresses hormone receptors. You might or might not already have had any chemotherapy, depending on what you and your doctor decided. If you get chemotherapy, you will enroll on this study after you have finished chemotherapy if you are still premenopausal.

If you have had a history of blood clots you might not be able to take part in this study. You will also not be able to be in the study if you have had your ovaries removed. You should not be in this study if you are pregnant or breastfeeding or wish to become pregnant within the next 5 years.

This form is to provide you with enough information so you can understand the possible risks and benefits of participating in this clinical trial, and decide whether or not you want to be part of this research study.

WHY IS THIS STUDY BEING DONE?

Treatment with hormones has been shown to help prevent breast cancers from coming back after they have been removed by surgery if the breast cancer has hormone receptors. The hormone generally used is tamoxifen, and it is usually given for five years. It has also been shown that suppressing (shutting down) the ovaries (which stops them from making hormones such as estrogen) helps prevent breast cancers from coming back in women who are premenopausal (women whose ovaries are still making hormones). This study is being done to see if shutting down the ovaries plus giving tamoxifen is better at preventing the return of breast cancer than just giving tamoxifen alone in premenopausal women. It will also test whether a newer hormone drug called exemestane plus

suppression of the ovaries is better than tamoxifen plus suppression of the ovaries. In addition the side effects of these different treatments will be studied.

Tamoxifen is standard therapy. Exemestane is a drug which is FDA approved for use in metastatic breast cancer for postmenopausal women, but its use in cancer that has not yet spread outside of the breast and its use in premenopausal women is experimental. The combination of tamoxifen or exemestane with ovarian suppression in women with early stage breast cancer is experimental.

There are different ways to suppress the ovaries, and you and your physician may choose to have the ovaries removed surgically, shut down by radiation treatments, or suppressed by you getting a monthly injection of a drug. Surgery and radiation are permanent. The ovaries may start working again when injections are stopped. The drug which is suggested for monthly injection on this study is triptorelin, which is not FDA approved for use in breast cancer, and its use for breast cancer is therefore experimental. In rare circumstances your physician may suggest a different drug for injection (goserelin), but it will not be provided by the study.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 3000 women will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

Treatment selection: No one knows which treatment is best for you. For this reason, the treatment you will receive will be decided by chance (like the flip of a coin). This is called randomization. Your chances of receiving tamoxifen, tamoxifen plus ovarian suppression or exemestane plus ovarian suppression are equal (1/3 chance of receiving any one of the treatments). Neither you nor your doctor will choose which group you will be in.

Arm A: If you get randomized to Arm A, you will get tamoxifen for five years at a dose of 20 mg per day. This is a pill that is taken by mouth each day.

Arm B: If you get randomized to Arm B you will get tamoxifen for five years plus ovarian suppression for five years. Tamoxifen is a pill that is taken by mouth each day. You and your doctor may choose whether to suppress the ovaries by surgery, radiation, or injection of a drug each month. The injections will be given into the muscle (intramuscular; IM). If you choose to suppress the ovaries by radiation, treatments will be given once a day for four or five days.

Arm C: If you get randomized to Arm C you will get exemestane for five years plus ovarian suppression for five years. Exemestane is a pill that is taken by mouth each day.

You and your doctor may choose whether to suppress the ovaries by surgery, radiation, or injection of a drug each month. The injections will be given into the muscle (intramuscular; IM). If you choose to suppress the ovaries by radiation, treatments will be given once a day for four or five days.

As described in detail below, hormone treatments produce some side effects. It is possible that your physician will recommend medications to help with these side effects. For women with vaginal dryness and/or dyspareunia (pain with intercourse) vaginal moisturizers and lubricants may be used. If these do not help the symptoms, local vaginal estrogens such as Estrin may be considered. If you have bothersome hot flushes your doctor might recommend a serotonin reuptake inhibitor (one of a group of drugs related to Prozac). Because any of the treatments in this study may increase the risk of osteoporosis, vitamin D and calcium supplements will be recommended for most women on this trial. Women who have evidence of bone density loss (osteoporosis) may be recommended to have specific treatments for osteoporosis, such as alendronate (Fosamax).

PROCEDURES THAT ARE PART OF REGULAR CANCER CARE AND MAY BE DONE EVEN IF YOU DO NOT JOIN THE STUDY:

You will have a full medical history and physical examination taken at the time you enter the study and every 3 months for the first year, every 6 months for the second to sixth year, and once a year thereafter. You will also have blood tests (about one tablespoon). A mammogram (breast x-ray), and a chest x-ray will be done at the time you enter the study if they have not already been done in the past 12 months. Your doctor may suggest other tests, such as a test for bone density and more frequent mammograms.

In the event of abnormal vaginal bleeding or pelvic discomfort, you should have a gynecological (female) examination because of the increased risk of uterine cancer in patients receiving tamoxifen.

PROCEDURES BEING DONE BECAUSE YOU ARE IN THIS STUDY:

Prior to enrollment in this study, lab work to check your circulating estrogen levels will be performed to confirm you are pre-menopausal.

At specified intervals during the study, you will be asked to fill out questionnaires that ask you how well you feel and what side effects you are having from the treatment. You will be given Quality of Life Questionnaires before you begin the study, every six months during the first and second years and once a year during years 3 to 6. If, for any reason, a question makes you feel very uncomfortable, you may leave the question unanswered. However, we would like to encourage you to answer all of the questions because your answers may help us better understand how the treatments influence the quality of patients' every day life.

If your surgery was a lumpectomy and you have not yet had radiation therapy, you will be given radiation therapy to the breast, regardless of which hormone treatment you are

on. Radiation therapy to the chest wall may also be given for some patients who have had a mastectomy. Your doctor will talk this over with you.

HOW LONG WILL I BE IN THIS STUDY?

You will receive the hormone treatment for 5 years unless there is evidence of disease recurrence. However you will continue to be followed on this study for the remainder of your life to determine if your cancer ever comes back.

You can choose to stop participating in this study at any time. However, if you decide to stop participating in the study, we encourage you to talk your doctor first.

It is possible, though not likely, that your participation in this study will be ended by your doctor or the investigators running the trial without your consent, either because it is felt to be in your best interest or because the study is being stopped.

WHAT ARE THE RISKS OF THE STUDY?

While on the study, you are at risk for side effects, as discussed below. You should discuss these with the researcher and/or your regular doctor. There also may be other side effects that we cannot predict. Other drugs may be given to make some of these side effects less serious and uncomfortable. Many side effects go away shortly after the drugs are stopped, but in some cases side effects can be serious, long-lasting or permanent. There may also be unexpected risks (risks not known about).

Your physician will be checking you closely to see if any of the side effects are occurring. Physical exam, routine blood tests and other tests (depending on the choice of therapy) will be done to monitor the effects of treatment. Your physician may prescribe medication to keep these side effects under control. Schedules and dosages may be also altered to reduce their frequency and intensity. You should report any side effect or symptom that you experience to your physician. Moreover, it is important that you tell your physician about additional medication that you take during or after the treatment. Your physician may also decide to stop the treatment early in case of blood clots, vaginal bleeding, abnormal lab values or any other serious toxicity.

Risks and side effects related to an injection to shut down the ovaries, such as triptorelin or goserelin, include:

Likely side effects: hot flushes, stopping of menstrual periods, inability to have children while receiving the injections, decrease in sex drive, and vaginal dryness and/or dyspareunia (painful intercourse).

Less frequent side effects: headache, tiredness, mood changes, sleep disturbance, nausea, back or joint pain, local irritation where the shots are given and slight rise in

cholesterol. Loss of bone mineral density (osteoporosis) may occur and may lead to broken bones.

Rare side effects: Skin rash, allergic reactions including swelling, low or high blood pressure, and elevated liver blood tests. Anaphylactic shock, a very severe allergic reaction that can cause death is quite rare, but has occurred

Risks and side effects related to surgery to remove the ovaries include:

Likely side effects: hot flushes, stopping of menstrual periods, inability to have children, decrease in sex drive, and vaginal dryness and/or dyspareunia (painful intercourse).

Less frequent side effects: headache, tiredness, mood changes, sleep disturbance, nausea, back or joint pain, and slight rise in cholesterol. Loss of bone mineral density (osteoporosis) may occur and may lead to broken bones.

Rare side effects: complications of the anesthesia or surgery itself, such as a wound infection. These will be described in more detail in a separate surgery consent.

Risks and side effects related to radiation to shut down the ovaries include:

Likely side effects: hot flushes, stopping of menstrual periods, inability to have children, decrease in sex drive, and vaginal dryness and/or dyspareunia (painful intercourse).

Less frequent side effects: headache, tiredness, mood changes, sleep disturbance, nausea, back or joint pain, and slight rise in cholesterol. Loss of bone mineral density (osteoporosis) may occur and may lead to broken bones.

Rare side effects: complications of the radiation might include nausea or tiredness

Risks and side effects related to tamoxifen include:

Likely side effects: hot flushes, night sweating, vaginal discharge or dryness, irregular periods, vulvar itching and nausea.

Rare side effects: Swelling, skin rash, and hair thinning. Tamoxifen may be associated with loss of bone mineral density in pre-menopausal women however minimizes bone mineral density loss in the menopausal state. An infrequent side effect is abnormal occurrence of blood clots. A blood clot in the leg can cause serious problems, including death, if it travels to the lungs. Women taking tamoxifen may be at a slightly higher risk for getting cataracts (a clouding of the lens inside the eye). Cataracts may lead to poor vision. Tamoxifen can raise sensitivity to blood thinners such as coumadin. Tamoxifen may cause changes in the lining of the uterus (endometrium).

In addition, for every 1000 patients who take tamoxifen each year, 1-2 patients have developed cancer of the uterine lining (endometrial cancer), and even fewer have developed a cancer of the uterine muscle (uterine sarcoma). In women who are getting

ovarian function suppression any vaginal bleeding should be reported to your doctor, as it may be a warning sign of uterine cancer. In women who are getting tamoxifen without ovarian function suppression it is normal to continue to have vaginal bleeding, but if this bleeding seems particularly heavy it should be reported to your doctor.

Risks and side effects related to Exemestane:

Likely side effects: Hot flushes, sweating, nausea, fatigue and flu-like symptoms (aches and pains). Furthermore headaches, insomnia, depression, dizziness, diarrhea, visual disturbances, blood clots and high blood pressure have been observed while taking exemestane. Exemestane may result in loss of bone mineral density (osteoporosis) which may lead to broken bones.

Less frequent side effects: Skin rash and hair thinning.

Reproductive risks (on any of the arms of this study): Because the drugs in this study can affect an unborn baby, you should not become pregnant while on this study. In general, if your ovaries are suppressed, you will not be able to become pregnant, but you cannot be certain about that. You should not nurse your baby while on this study. Ask about counseling and more information about preventing pregnancy.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope the information learned from this study will benefit other patients with breast cancer in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, your doctor may recommend that you receive hormonal therapy with tamoxifen for 5 years or some other form of hormonal therapy not given as part of this study.

No hormonal therapy at this time is also an option but unlikely to be recommended by your doctor.

Please talk to your doctor about these and other options.

WHAT ABOUT CONFIDENTIALITY?

Every effort will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

If at any time you wish to withdraw from the study you may do so. In that case, we would continue to store the data already collected, and with your agreement, we would like to continue to collect basic information about your health status in the future. If however, you wish to withdraw from the study and do not want data relating to you

personally to be stored, then the data already collected about your health will be 'anonymised' (that means, it cannot be linked to you in any way), and no further data will be collected. Please notify the IBCSG through your doctor by submitting a written statement.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as:

- International Breast Cancer Study Group (IBCSG), the research group coordinating this study.
- The Northwest Community Clinical Oncology Program (NWCCOP).
- The research ethics committee who oversees the ethical conduct of this study in your hospital/clinic (may be known as IRB, institutional review board)
- The U.S. National Institutes of Health (NIH) and National Cancer Institute (NCI)
- U.S. Food and Drug Administration (because it oversees the use of new drugs in the U.S.)
- Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute, (NCI) to provide greater access to clinical trials
- Therapeutic Products Directorate of Health Canada (because it oversees the use of new drugs in Canada).
- Pharmacia (the company supplying the exemestane and triptorelin).

WHAT ARE THE COSTS?

Exemestane and triptorelin will be supplied to you on this study free of charge if you are randomized to a treatment using one of those drugs. If these drugs become commercially available for the treatment of early breast cancer there is a remote possibility that you or your insurance company may be asked to purchase subsequent supplies. All other expenses, including the cost of tamoxifen, and surgery or radiation to shut down your ovaries will be charged to you or your insurance company. Taking part in this study may lead to added costs to you or your insurance company. Please ask about any expected added costs or insurance problems.

In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury.

Your or your insurance company will be charged for continuing medical care and/or hospitalization.

You will receive no payment for taking part in this study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact *the Northwest Community Clinical Oncology Program, 253-403-1461*. For questions about your rights as a research participant, call *MultiCare Health System Institutional Review Board at 253-403-3844*. The Institutional Review Board (IRB) is a group of people who review research studies to protect your rights.

The physician(s) involved with the medical care of the patient is available to answer **ANY** question(s) concerning the research/drug program. In case of a problem or an emergency, the physician should be contacted by telephone (see cover sheet).

You may also call the Project Office of the NCI Central Institutional Review Board (CIRB) at 888-657-3711 (from the continental US only).

WHERE CAN I GET MORE INFORMATION?

You may call the NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

Visit the NCI's Web sites

cancerTrials: comprehensive clinical trials information

[http://cancer.gov/clinical trials](http://cancer.gov/clinical%20trials)

CancerNet : accurate cancer information including PDQ

<http://cancer.gov/cancerinformation>

You will get a copy of this form. Upon request, you will also receive a copy of the protocol (full study plan).

SIGNATURE

You are deciding whether or not to take part in this study. If you sign, it means that you have decided to volunteer to take part in this study, and that you have read and understood all the information on this form.

Patient's name (printed or typed)

Patient's Signature Date

Physician name (printed or typed)

Physician Signature Date

Signature of person conducting the
Informed consent discussion

Date

A Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane for Premenopausal Women with Endocrine Responsive Breast Cancer.

TISSUE CONSENT FORM

The researchers doing this study are interested in doing research studies on tissue samples from your cancer now and in the future to better understand the nature of breast cancer and how patients respond to treatment. The research that may be done with your samples is designed to help people in the future who have the same kind of cancer as you have.

The collection of these tissue samples is part of this study. The pathology review at a central laboratory or institute is a requirement for this study. Testing of genes, which may be inherited in your family, is not part of the pathology review of this study. Studies will include a central review of hormone receptor status and HER2 status.

Tissue samples may be used for research purposes only and will not be sold. In the future, researchers may want to do genetic testing with your tissue (this is testing for diseases which can be inherited). If this happens, you will be contacted and will be asked to give permission for this genetic testing. These tests will not be done without your permission.

The only identification that will be on your tissue samples kept in the laboratory will be your hospital identification number and study code. Reports about any research done with your samples will not be given to you or your doctor. These reports will not be put in your medical records. Any research using your samples will not affect your care.

In the future, people who do research with your sample may need to know more about your health. While the researchers coordinating this study may give them reports about your health, they will not give them your name, address, phone number or any other information that will let the researchers know who you are.

I agree to allow that tissue samples from my tumor be collected for the purposes described here.

Yes____ No____ Initials_____

In addition to the studies specific to this clinical trial, it is possible that researchers might wish to use your tissue specimen for other investigations (research). The results of tissue (specimen) bank research may help find new ways to learn about prevent, or treat cancer and other diseases. Please read each sentence below and think about your choice. After reading each sentence, circle and initial the answer that is right for you. If you have any questions, please talk to your doctor or nurse, or call the National Cancer Institute's Cancer Information Service at 1-800-422-6237 (1-800-4-CANCER).

1. My tissue (specimen) may be kept for use in research to learn about, prevent, or treat cancer.

Ye____ No____ Initials_____

2. My tissue (specimen) may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

Yes____ No____ Initials_____

3. Someone representing the National Cancer Institute or the International Breast Cancer Study Group may contact me in the future to ask me to take part in more research.

Yes____ No____ Initials_____

Signature of Patient

Date

Signature of Witness

Date

**Authorization (Permission) to Use or Disclose (Release)
Identifiable Health Information for Research**

Participant's Name: _____

Birth Date: _____

1. *What is the purpose of this form?*

The International Breast Cancer Study Group (IBCSG) is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers at (your institutions) would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your personal health information, you must sign and date this form to give them your permission.

2. *What personal health information do the researchers want to use?*

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter an International Breast Cancer Study Group research study, information that will be used and/or released may include the following:

- the history and diagnosis of your disease;
- specific information about the treatments you received, including previous treatment(s) you may have had;
- information about other medical conditions that may affect your treatment;
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, x-rays, and pathology results;
- information on side effects (adverse events) you may experience, and how these were treated;
- long-term information about your general health status and the status of your disease;
- data that may be related to tissue and/or blood samples that may be collected from you; and
- numbers or codes that will identify you, such as your social security number and medical record number.

As well as data collected from the items listed above, for the IBCSG protocol information will be collected on your family history of breast cancer, quality of life questions and scans done to measure the density of your bones.

You may request a blank copy of the IBCSG data forms from the study doctor or his/her research staff to learn what information will be shared.

3. *Why do the researchers want my personal health information?*

The physicians and other personnel at the site *[and/or physician organization]* named above will collect your health information and share **it with IBCSG, if you enter an IBCSG research study** researchers will use your information in their cancer research study. The research being considered is titled, **CTSU IBCSG 24-02: A Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane as Adjuvant Therapies for Premenopausal Women with Endocrine Responsive Breast Cancer. The purpose of the study is to compare different methods of hormonal suppression in women with breast cancer that is sensitive to the hormone estrogen. The study will also look at overall quality of life with the different treatment regimes including side effects of early menopause, long-term survival and incidence of breast cancer reoccurrence. More information about this study is available in the study specific informed consent document you will be asked to sign.**

4. *Who will be able to use my personal health information?*

The site and physician organization (if any) named above will use your health information for research. As part of this research, they may give your information to the following groups taking part in the research, and may also permit these groups to come in to review your original records so that they can monitor their research study.

Your physicians will collect your health information and share it with the Statistical Office at the Dana Farber Cancer Center in Boston, MA., and the Data Management Center at Frontier Science in Amherst, NY. In addition the following entities are involved with the coordination of this study and will have access to data collected on the study:

- Cancer Trials Support Unit (CTSU), a pilot project of the NCI, will act as coordinating center for conduct of the trial in North America. It is located in Rockville, MD.
- IBCSG Coordinating Center in Bern, Switzerland will oversee the study and Quality of Life substudy.
- The IBCSG central laboratory for this trial that studies and retains your tissue samples, if you give separate consent for them to be submitted.
- The pharmaceutical partner for this study is Pharmacia in Peaback, NJ.
- Public Health agencies and other government agencies as authorized or required by law, including the U.S. Food and Drug Administration, Canadian Therapeutic Products Directorate of Health Canada and other governmental agencies overseeing the use of new drugs used in this trial.

The organizations listed above will use your information for the purpose of cancer research.

5. *How will information about me be kept private?*

The IBCSG will keep all patient information private to the extent possible, even though the IBCSG is not required to follow the federal privacy laws. Only researchers working with the IBCSG will have access to your information. The IBCSG will not release personal health information about you to others except as authorized or required by law. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

6. *What happens if I do not sign this permission form?*

If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. *If I sign this form, will I automatically be entered into the research study?*

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.

8. *What happens if I want to withdraw my permission?*

You can change your mind at any time and withdraw your permission to allow your personal health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the person below. He/she will make sure your written request to withdraw your permission is processed correctly.

Karyn Hart, RHIT, CCRP
Program Coordinator
Northwest CCOP
315 Martin Luther King Jr., Way
Tacoma, WA 98405
(253) 403-1461

9. *How long will this permission last?*

If you agree by signing this form that researchers can use your personal health information, this permission has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding access to my personal health information?

You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your personal health information kept by the Northwest CCOP. You do not have the right to review and/or copy records kept by the IBCSG or other researchers associated with the research study.

Signatures

I agree that my personal health information may be used for the research purposes described in this form.

Signature of Patient
or Patient's Legal Representative: _____ Date: _____

Printed Name of Legal Representative (if any): _____

Representative's Authority to Act for Patient: _____

Signature of Person Obtaining Permission: _____ Date: _____

Printed Name of Person Obtaining Permission: _____